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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/312,485	05/17/1999	PATRICE DEBREGEAS	065691/0163	2681

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/312,485

Applicant(s)

DEBREGEAS ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-20 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-20 and 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                              |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/13/2005</u> | 6) <input type="checkbox"/> Other: _____                                                |

8.0.0.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 13, 2005 has been entered.

Claims 12-20, 23-25 are pending. Rejections of record are withdrawn in view of the newly amended claims. New grounds of rejection are as follows.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-25, 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamada US Patent 5,384,130 in view of Menzi US Patent 6,056,949 and Makino US Patent 5,026,560.

The instant claims are directed to methods of preparing a granule comprising the steps of coating a neutral core having a particle size of 200 to 1600  $\mu\text{m}$  and consisting of sugar, starch, mannitol, sorbitol, xylitol, cellulose, talc or mixture thereof with a layer containing a plant substance.

Kamada teaches methods of preparing coated granules comprising an inert core consisting of microcrystalline coated with an active agent. (abstract). The core granule used by Kamada has a 100 to 1000  $\mu\text{m}$  particle size which falls within the particle sizes of instant claims 23, 16-17. Kamada teaches that aside from microcrystalline cellulose the spherical seed cores can contain other sugars and starch. (see col 4, lines 40-43). The coating used by Kamada contains an active agent and a binder such as PVP (col 5, lines 14-30). Kamada describes that the coating can be applied in the form of a dry powder or liquid extracts or solutions by spraying or using fluidized bed coating machine (see col 4, lines 58-68; col 5, lines 1-26 and lines 38-66). Thus, Kamada meets the limitations of the instant claims 12-13, and 20. Kamada fails to explicitly teach the starch/sucrose ratios of the instant claim 24-25 and further the use of plant substance containing extracts in his coating solutions.

Menzi teaches spherical granules coated with plant extracts. Menzi's core is mainly of carbohydrates (such as starch, sucrose, lactose or maltodextrin) that are sprayed coated by emulsions (col 2, lines 6-30, example). The coating emulsions of

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Menzi can comprise plant extract (col 2, lines 20-25, lines 40-47; col 5, lines 63-67; col 6, lines 20-22 and lines 51-56). In fact, Menzi uses coating material such as fruit flavor, vegetable proteins, lemongrass oil, lemon flavour that falls within the instant limitations "Plant Substance." (see col3-4, examples 1-6; col 6, lines 27-32). Menzi specifically teach the use of flavorant or odorants in his coating emulsion that can contain various modified cellulose (encompassing hydroxymethylcellulose), plant extract, and/or synthetic material such as PVP. (see col 2, lines 6, lines 50-59; col 2, lines 46-48). Menzi also teaches water and ethanol as their solvent of choice. (see col 2, lines 28-30). Menzi does not explicitly uses a PVP binder.

Makino's teachings are complementary to those of Kamada and are in the same field of endeavor. Makino is used to show the typical ranges of sucrose and starch in a neutral core. Makino teaches methods of preparing coated granules comprising a neutral core coated with any suitable active substance including nutritional substances abstract, col 2, lines 1-27; col 4-6). The core used by Makino is a nonpareil produced by 75% sucrose and 25% starch. (see col 3, lines 29-34). The core can be coated with any drug substance and an excipient/binder such as PVP. (see col 3, lines 45-52). Makino's core is about 200  $\mu\text{m}$ . Makino fails to explicitly use a drug from a plant source, and further use cores within the sizes of 900-1400  $\mu\text{m}$ .

Nevertheless, it would have been obvious to one of ordinary skill in the art at the time of invention to replace the coating solutions of Kamada with the coating solutions of Menzi and prepare stable plant substance containing granules, and then optimize the

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starch/sucrose ratios in the neutral core following the teachings of both Kamada and Makino.

One of ordinary skill in the art would have been motivated to do such modifications in Kamada's process, because as described by Menzi, coating a neutral core with a plant extracts of Menzi would improve its aesthetic properties such as flavor and odor. The ordinary skill in the art would have had a reasonable expectation of success in coating the neutral cores of Kamada with a plant containing coating solutions of Menzi, because Menzi already prepares similar free-flowing stable granules with improved flavor and odor. Finally, the ordinary skill in the art would have had a reasonable expectation of success in optimizing the ratios of sucrose and starch in the neutral cores of Kamada, because the teachings in the art, including those of Makino, provides for a general suitable range of ratios for sucrose and starch in a neutral core.

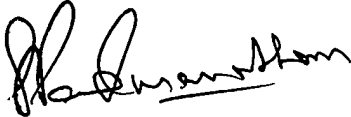
### ***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SS



**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**